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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) VAC.702.US	
		Application Number 10/090,358-Conf. #3855	Filed March 4, 2002
		First Named Inventor David Tumey	
		Art Unit 3761	Examiner M. J. Hand
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p>			
<p>I am the</p> <p><input type="checkbox"/> applicant /inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>47,649</u></p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. _____</p> <p> _____ Signature</p> <p>_____ Robert C. Hilton Typed or printed name</p> <p>_____ (214) 758-6641 Telephone number</p> <p>_____ January 18, 2008 Date</p>			
<p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>			
<p><input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.</p>			



Docket No.: VAC.702.US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/090,358 Confirmation No.: 3855
Applicants : David Tumey
Filed : March 4, 2002
TC/A.U. : 3761
Examiner : Hand, Melanie Jo
Docket No. : VAC.702.US
Customer No.: 60402

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The Examiner has twice rejected the Applicant's claims. The Applicant files this brief in support of the accompanying request for review, in accordance with the provision set forth in the Official Gazette Notice of July 12, 2005. The Applicant respectfully requests reconsideration of this application in light of the remarks set forth below.

REMARKS

The Applicant respectfully submits that the rejections of claims 1-10 under 35 U.S.C. § 103 contain clear legal and factual deficiencies. In an Office Action dated October 18, 2007, the Examiner rejected claim 1 as unpatentable over U.S. Patent No. 4,382,441 ("Svedman") in view of any of U.S. Patent No. 5,237,523 ("Bonne"), U.S. Patent No. 5,437,184 ("Shillady"), and U.S. Patent No. 6,192,753 ("Czarnek");¹ rejected claims 2 and 3 as being unpatentable over these references in further view of U.S. Patent 5,611,846 ("Overton"); rejected claim 4 as being unpatentable over Svedman and any of Bonne, Shillady, or Czarnek in further view of U.S. Patent No. 6,017,440 ("Lewis"); rejected claims 5,6, and 10 as being unpatentable over Svedman and any of Bonne, Shillady, or Czarnek in further view of U.S. Patent No. 6,458,109 ("Henley"); rejected claim 7 as being unpatentable over Svedman and any one of Bonne, Shillady, or Czarnek in further view of U.S. Patent No. 855,570 ("Scherson"); rejected claim 8 as being unpatentable over Svedman and any of Bonne, Shillady, or Czarnek in further view of U.S. Patent No. 6,398,767 ("Fleischmann"); and rejected claim 9 as being unpatentable over Svedman and any of Bonne, Shillady, or Czarkek and Henly and in further view of U.S. Patent No. 4,955,391 ("Parker"). The Applicant requests a finding that these rejections are improper and that the claims be allowed.

Claim 1 and its dependents are allowable because the cited references do not teach or suggest the claimed invention as a whole. Among other things, the references do not teach or suggest a negative pressure therapy device that comprises "a fluid compositional sensing device."

The Examiner concedes that Svedman is deficient, but concludes nonetheless that it would have been obvious to one of ordinary skill in the art to modify the device of Svedman so as to include a fluid compositional sensing device "such as a flow meter, which also senses changes in temperature, in place of said temperature sensor." (Office Action of 10/18/07, at 3.) In support, the Examiner cites Bonne, Shillady, and

¹ The Examiner identifies the last reference as "Czernak (U.S. Patent No. 6,192,573)," but U.S. Patent No. 6,192,573 is issued to Hahakura et al. and appears to have no relevance to the Examiner's rejections. In the interest of efficient prosecution, the Applicant assumes that the Examiner intended to cite U.S. Patent No. 6,192,753, issued to Czarnek. The Applicant respectfully requests confirmation or clarification from the Examiner in any subsequent correspondence.

Czarnek for the proposition that “it was known in the art to use flow meters to detect changes inflow [sic] due to temperature or change in composition that were calibrated for those parameters to obtain temperature and compositional data.” (*Id.*)

With respect to Bonne and Czarnek, neither reference appears to have any relevance to detecting “change in composition,” as the Examiner contends. Bonne “relates to fluid flow *measurement* and, more particularly, addresses overcoming inaccuracies in flow measurement.” Bonne, *supra*, at col. 1, ll. 13-15 (emphasis added). Bonne provides “a method which can be used to correct the measured flow for changes in . . . the composition of gas . . . relative to the calibration gas composition.” *Id.* at col. 1., l. 65-col. 2., l. 3. Bonne is silent on any method or device for identifying a gas composition. In fact, the composition of a gas appears to be irrelevant for the purposes of correcting flow measurements, and Bonne presumes that certain characteristics of the gas are already known. See *id.* at col. 2, ll. 12-60 (correction equations depend only on the measured gas’s thermal conductivity, specific heat, and absolute temperature). Thus, Bonne does not appear to support the Examiner’s conclusion that it was known in the art to use “flow meters” to “obtain . . . compositional data.”

Czarnek “relates to a sensor system for monitoring fluid level and displacement.” Czarnek, *supra*, at col. 1, ll. 15-20. The only reference to the “composition” of a fluid in Czarnek appears in a recitation of problems associated with sensors that are *affected* by variations in compositions. The Applicant is unable to discern any suggestion that the Czarnek fluid level sensor could also be used to obtain compositional data, and the Examiner has cited no particular passage to support such a conclusion.

Shilladay is likewise insufficient to support the Examiner’s conclusion. Like Czarnek, Shilladay is related to detecting a fluid level in a fluid reservoir. Shilladay, *supra*, at col. 1, ll. 7-11. Shilladay describes an apparatus that is merely capable of “determining *differences* in the composition” of fluids being measured. *Id.* at col. 3, ll. 8-13 (emphasis added). This difference can be detected by a relative phase difference between two signals because the dielectric constant of various fuels can vary widely, such as when a fuel contains water. *Id.* at col. 10, ll. 43-52. Clearly, determining

differences in fluid compositions is not the same as determining the compositional characteristics of a fluid, as required in claim 1.

Moreover, none of the cited references appears to be even remotely related to the medical arts. Here, the Applicant has described a means for diagnosing the nature or specific type of infection present at a wound site during the utilization of an airtight dressing, among other things. (See, e.g., Spec. at para. 13.) By its own terms, Bonne addresses “needs and problems *in the field of hot element (wire or film) gas flow measurements.*” Bonne, *supra*, at col. 1, ll. 65-67 (emphasis added). Czarnek addresses problems in the field of crude oil storage. Czarnek, *supra*, at col. 1, ll. 15-20. Shilladay is directed to those skilled in the automotive industry. See, e.g., Shilladay, *supra*, at col. 1, ll. 15-20. Given the wide disparity of fields from which the Examiner has drawn upon, the Examiner’s explanation of why it would have been obvious to a person of skill in the medical arts to combine these references is inadequate. See, e.g., *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007) (requiring an alleged reason for combining the prior art to be supported by articulated reasoning with some “rational underpinning” to support the legal conclusion of obviousness).

Accordingly, the rejections of claim 1 and its dependents are legally and factually deficient and should be withdrawn. The rejections of claim 6 and its dependents are deficient for similar or analogous reasons and should be withdrawn as well.

Claim 6 and its dependents also are allowable because Svedman does not suggest all of the claimed limitations. Among other things, Svedman does not suggest a negative pressure therapy device that comprises “a fluid compositional sensing device.” The Office Action concedes that Svedman is deficient, but argues that it would be obvious to one of ordinary skill in the art to substitute a fluid compositional sensing device for the temperature sensor taught by Svedman. (Office Action of 10/18/07, at 6.)

As already noted, the Applicant has described a means for diagnosing the nature or specific type of infection present at a wound site during the utilization of an airtight dressing, among other things. (See, e.g., Spec. at para. 13.) Claim 6 requires a fluid compositional sensing device to determine the compositional characteristics of wound fluid. In contrast, the temperature sensor of Svedman is used only to regulate the

application of heat to a fluid, and Svedman teaches only that heat may be applied to the fluid to therapeutically temper tissue. The Office Action posits that a temperature increase signals the presence of bacterial infection, but this position is simply inaccurate to the extent that it suggests that a temperature increase *always* signals the presence of bacterial infection. Even Svedman indicates that an increase in temperature merely indicates that too much heat is being applied for a desired treatment. Svedman is completely devoid of any diagnostic application, *i.e.*, identifying the composition of a fluid. One of ordinary skill in the art would have no apparent reason to look to Svedman to provide a means for diagnosing unfiltered wound fluid composition. The Office Action's broad, conclusory statements to the contrary are legally and factually deficient. See *KSR*, 127 S. Ct. at 1741 (broad conclusory statements of suggestion or motivation standing alone are not sufficient).

Applicants believe a fee of \$510.00 is due with the filing of this Pre-Appeal Brief. Credit Card Payment Form SB-2038, with a signature from an authorized cardholder, is enclosed. The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-2816, under Order No. 023104.0702PTUS. A duplicate copy of this paper is enclosed.

Respectfully submitted,



Robert C. Hilton
Reg. No.: 47,649

Date: 1/18/08

For Applicants:
Kinetic Concepts, Inc.
Legal Department – Intellectual Property
P.O. Box 659508
San Antonio, Texas 78265-9508
Telephone: 210.255.6855
Facsimile: 210.255.6969